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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,214	01/28/2004	Ray Bojarski	00167-524001 / 02-31-0483	7657
7590 Joel R. Petrow, Esq. Chief Patent Counsel Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 04/06/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/765,214	Applicant(s) BOJARSKI ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-10,12,13,16-21 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-10,12,13,16-21, and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 20, 21, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mericle et al. (5,423,837). Mericle et al. also disclose, at least in figures 2 and 4 and in col. 3, lines 22-53 and col. 4, lines 45-57; a method including coupling a body (6) to an end of a tube (26), the body defining a tapered hole (16) and a slot (30); guiding a member ("suture material") into the tube (for cutting of the suture material at the distal tip of 26, where shearing of the suture material or cutting of the suture material against the anvil-like, inner distal end surface of element 6 inherently results in a portion of suture material moved within the "circular cutting edge" of tube 26) through the

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tapered hole, the tapered hole acting to guide the member when advanced into the tube from a larger opening (24) of the tapered hole to a smaller opening (28) of the tapered hole (see col. 4, lines 45-48); and separating the body and the member by passing the member through the slot, where coupling includes receiving the end of the tube in a bore in the body (at the proximal portion of 6 and distal of 14), the bore communicating with the tapered hole, and where the body is decoupled from the end of the tube (when the tube is retracted by spring 18).

4. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. (6,430,804). Nelson et al. disclose, at least in figures 1 and 4-7, a device with a body (60) including a first terminal end portion (64) defining a tapered hole (78), a second terminal end portion (62) defining a bore, and a projecting surface (74 and/or 68) formed on an internal surface of the body at an intersection between the tapered hole and the bore, the body defining a slot (72) communicating with the hole and the bore or a separating means, where the bore has a constant diameter, where the slot extends from the tapered hole and the bore to an external surface of the body, where the slot (72) extends from a terminal end of the first portion to a terminal end of the second portion or from the first terminal end portion to the second terminal end portion, and where the device includes a cylindrical handle (50 or 92) connected to the body (via 52 and 20 or 94) and projecting on only one side opposite to the slot.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 3, 6, 8-10, 12, 16, 17, 19, 24-26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (6,430,804 or Nelson '804) in view of Nelson et al. (4,798,554 or Nelson '554). Nelson '804 discloses the invention substantially as claimed. Nelson '804 discloses, at least in figures 1 and 4-7, a device with a body (60) including a first portion (64) defining a tapered hole (78) configured for guiding a member (82) into a tube that can be coupled to the body; a second portion (62) defining a bore; the bore having a diameter greater than a width of the narrowest portion of the tapered hole (i.e., the width between an inner edge of element 74 and an edge of the tapered hole or element 76); a projecting surface (74 and/or 68) formed on an internal surface of the body at an intersection between the tapered hole and the bore, where the bore has a constant diameter, and where the device includes a handle

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(66, 50, or 92) extending from the body, where the width of the tube opening is substantially (largely, but not wholly) the same as the width of the narrowest portion of the tapered hole (at 76). However, Nelson '804 does not disclose that the body defines a slot communicating with the hole and the bore for separating the body and the member while the member remains in the tube, the slot extending along the entire length of the body and extending from the tapered hole and the bore to an external surface of the body or the slot extending to an end of the body. Nelson '804 also does not disclose a tube or that the tapered hole is configured for guiding a member into a tube coupled to the body. Nelson '554 teaches, at least in figures 1 and 12 and col. 3, line 37 to col. 4, line 6; col. 3, lines 14-20; col. 6, lines 35-50; and col. 6, line 61 to col. 7, line 11; a body (1 or 20) with a slot (13 or 38) extending along the entire length of the body and a tube (2 or 28). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Nelson '554, to modify the device of Nelson '804 to include a slot and tube as claimed. A slot as claimed would allow rapid insertion of a balloon into the body, while a tube as claimed, would provide a handle for grasping of the combination of the balloon and body.

7. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson '804 in view of Nelson '554, and further in view of Stivers (2,882,645). Nelson '804 in view of Nelson '554 discloses the invention substantially as claimed, but does not disclose that the bore is tapered. Stivers teaches, at least in figure 2 and in col. 2, lines 1-5, a device including a body having first and second portions, where the bore of the second portion (11) includes a tapered bore. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made, in view of Stivers, to modify the bore of the device of Nelson '804 in view of Nelson '554, so that it is tapered. Such a modification would allow the device of Nelson '804 in view of Nelson '554 to not only contain the tail of a balloon, the tapered bore would allow securement of the tail to a reed.

8. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson '804 in view of Nelson '554, and further in view of Mason (4,145,838). Nelson '804 in view of Nelson '554 discloses the invention substantially as claimed, but does not disclose a member comprising a suture thread. Mason teaches, at least in figures 1-3 and col. 1, line 58 to col. 2, line 17; a body (2) for guiding a member (3) including a suture thread (4). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Mason, to include a suture thread with a member of Nelson '804 in view of Nelson '554. A suture thread would allow grasping of the combination of a body and a balloon, while the balloon is being secured to the body, and prevent the balloon from inadvertently floating away.

Response to Amendment

9. Applicant's arguments with respect to claims 1, 3, 4, 6-10, 12, 13, 16-19, 24-26, 30, and 31 have been considered but are moot in view of the new ground(s) of rejection. With respect to arguments regarding the rejection of claims 20, 21, 27, and 28 and based on Mericle et al. have been considered but are not persuasive. That is, Mericle et al. indeed disclose the method, where the tapered hole acts to guide the member

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when advanced into the tube (at cutting of the suture material) from a larger opening (24) of the tapered hole to a smaller opening (28) of the tapered hole (see col. 4, lines 45-48).

Applicant's arguments with respect to the rejection of claims 29 and 30 based on Nelson '804 have also been considered but are not persuasive. Nelson '804 indeed disclose a cylindrical handle connected to the body. The ENCARTA World English Dictionary defines "connect" to include to "link two things: to join two or more people, things, or parts" or to "associate somebody or something with another." And given the broadest reasonable interpretation, the cylindrical handle (50 or 92) is connected, i.e., linked to or associated with the body via 52 and 20 or 94. Moreover, the bore of the second portion of the body has a diameter that is indeed greater than a width of the narrowest portion of the tapered hole, where the width of the narrowest portion is deemed to be the distance between an edge of element 74 and the narrow edge of the tapered hole or element 76.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773